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those which are not. Therefore it is in fact, consistent with the use of the term "non-continuous" in defining a coating.

Applicant respectfully requests withdrawal of the rejection of claims 1, 3, 23 and 27 under 35 U.S.C. §112.

35 U.S.C. §103(a)

Claims 1, 3-8 and 23-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Porter et al. in view of Muni and (Sahatjian or Wang et al.). The Office Action asserts that the referenced patent discloses an insertable medical device having a protective surface coating, the coating comprising a polymer selected from a group consisting of thermoplastic polymers and thermosetting polymers, and the coating being non-continuous on the medical device.

Applicants traverse the rejection.

Independent claims 1 and 27 of the present invention are directed to a *medical balloon having a substantially uniform non-continuous or a discontinuous coating*.

Porter et al. was discussed in the previous response mailed. Porter et al. describes a fiber composite *stent*. The stent is made up of a biocompatible fibrous material which is coated, impregnated, filled, or otherwise treated with a curable material so that the fiber composite can be suitably shaped to support a portion of a body lumen and then cured to maintain the shape. *To reduce the risk of toxicity from the curable material prior to curing, the stent can further include a layer of a biocompatible material which encapsulates the curable fiber composite and serves as a barrier between the stent and any circulating blood, and between the stent and the lumen wall.*

The coating on the stent is continuous because it states that the layer of biocompatible material *encapsulates* the curable fiber composite and acts as a barrier between the stent and any circulating blood.

Muni describes an improved catheter shaft to reduce cost and improve performance. In one aspect, a method is provided to produce a nonuniform polymer coating on a *catheter shaft to reduce friction* and to maintain a catheter with a low profile.

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There would be no motivation to dispose the nonuniform coating of Muni on the composite fiber stent of Porter et al. because the material of Muni is sputter coated to produce a nonuniform coating (see the Summary of the Invention, col. 2, lines 13-21). Sputter coating such a nonuniform coating would not result in encapsulation of the curable fiber composite stent as described in Porter et al. and would therefore not be able to prevent contact of the curable material with circulating blood or the body lumen because some of the curable material would be left exposed to the environment using a nonuniform coating.

Furthermore, it is clear that the problem which is being solved by Porter et al. is very different from that which is being solved by Muni. Muni is sputter coating a catheter with Teflon or similar material to produce a nonuniform coating to maintain a surface with a low friction coefficient while keeping the profile of the catheter low. See the Summary of the Invention. Porter et al. is coating to encapsulate a curable material to prevent contact of the curable material with the surrounding environment.

Consequently, Applicants submit that there would be no motivation to combine the nonuniform coating of Muni with the stent of Porter et al.

Furthermore, even if there was some motivation to combine these references, disposing the nonuniform coating of Muni on the stent of Porter et al. does not lead one of skill in the art to a *balloon catheter* having a non-continuous coating. In order to sustain an obviousness rejection, the combination of references must have all the elements of the claimed invention. Applicants submit that the combination does not. Therefore, Applicants submit that a rejection of claims 1, 3-8 and 23-29 under 35 U.S.C. §103(a) as being obvious over Porter et al. in view of Muni fails.

The Office Action further introduces Sahatjian or Wang et al. to demonstrate that it is conventional and well known in the art to use coatings on dilatation balloons.

First of all, Applicants do not dispute that using coatings on dilatation balloons is known.

Sahatjian, US 5304121 describes a drug delivery system which makes use of a hydrogel polymer.

Wang et al., US 5490839 describes a balloon for a dilatation catheter comprising a balloon wall, the wall having an exterior polymeric coating, the coating being set to prefer a

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predetermined low-profile deflated configuration of the balloon, such as a trifold configuration.

Neither Sahatjian nor Wang et al. describe the use of a noncontinuous coating.

Combining the drug delivery of Sahatjian or the polymeric coating of Wang et al. which is set to prefer a predetermined low-profile deflated configuration of the balloon, with the stents of Porter et al. does not lead one of ordinary skill in the art to the noncontinuous coatings described and claimed in the present invention.

Thus, the combination of any of the patents with Porter et al., regardless of what they are directed to, does not lead one of ordinary skill in the art to a balloon with a substantially uniform noncontinuous protective coating disposed thereon.

Applicants respectfully request withdrawal of the rejection of claims 1, 3-8 and 23-29 under 35 U.S.C. §103(a) as being unpatentable over Porter et al. in view of Muni and (Sahatjian, US 5304121 or Wang et al., US 5490839).

Claims 1, 3-8 and 23-29 have been rejected as being unpatentable over Yang et al. in view of Porter et al. and Muni.

The Office Action asserts that Yang et al. discloses a medical balloon insertable in the body having a uniform protective coating. The Office Action asserts that based on the teachings of Porter et al. and Muni, it would have been obvious to modify the balloon coating in Yang et al. with a polymer selected from the group consisting of thermoplastic polymers and thermosetting polymers and a non-continuous coating since said modifications are well known in the art.

Yang et al. discloses a two coating system in which the first coating includes a lubricious hydrogel, and the second coating is disposed on the first coating to help prevent the premature absorption of moisture by the hydrogel.

Porter et al. is described above and discloses a curable fiber composite stent with *a biocompatible material which encapsulates the curable fiber composite and serves as a barrier between the stent and any circulating blood, and between the stent and the lumen.*

Muni is also described above and again discloses in one aspect, a method to produce a nonuniform polymer coating on a *catheter shaft to reduce friction* and to maintain a catheter with a low profile. Sputter coating is disclosed to produce the nonuniform coating.

There would be no motivation to combine Muni with Yang et al. because there is

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no motivation to provide a nonuniform sputter coating on the balloon of Yang et al. With sputter coating, it would be difficult to ensure that the second coating which is disposed on the first coating having the hydrogel, would be sufficient to prevent the hydrogel from absorbing moisture because it would leave part of the hydrogel coating exposed. There is no suggestion from Yang et al. that a nonuniform sputter coating could be employed in the invention therein.

Furthermore, the present invention describes a substantially uniform, discontinuous coating, not a nonuniform coating such as that which one would get by sputter coating. Sputter coating by its very nature would not provide a uniform coating pattern. Therefore, even if there was motivation to combine the references, the combination does not lead one of skill in the art to the present invention.

Combining the coating of Porter et al. with Yang et al. would arrive at an encapsulated medical device as described by Porter et al. and thus does not lead one of skill in the art to employ a balloon having a substantially uniform noncontinuous coating on a balloon as described and claimed by the present invention.

Therefore, there is no motivation to combine Muni with Yang et al. and the combination of Porter et al. with Muni does not lead one of ordinary skill in the art to the balloon of the present invention.

Based on the foregoing arguments, Applicants respectfully request withdrawal of the rejection of claims 1, 3-8 and 23-29 under 35 U.S.C. §103(a) as being unpatentable over Yang et al. in view of Porter et al. and Muni.

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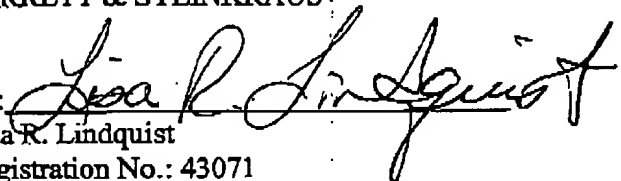
CONCLUSION

Claims 1, 3-8 and 23-32 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing arguments, Applicants respectfully request withdrawal and an early allowance of the claims as presented.

Respectfully submitted,

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